January 6, 2005

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SUPPLEMENT TO CITIZEN PETITION

Docket No. 2004P-0239

The undersigned, on behalf of GlaxoSmithKline (GSK), submit this supplement pursuant to 21 CFR § 10.30(g) to the citizen petition filed with the Food and Drug Administration (FDA) on May 19, 2004 (FDA Docket No. 2004P-0239/CP1) (the Petition). The Petition requests that FDA complete the development of a guidance document setting forth a scientifically valid methodology for establishing the bioequivalence of nasal suspension products, and refrain from approving abbreviated new drug applications (ANDAs) for fluticasone propionate nasal spray products, until a final guidance document has issued. *See* Petition at pages 2-3 for a full statement of "ACTIONS REQUESTED." GSK is the sponsor of the pioneer product FLONASE® (fluticasone propionate) Nasal Spray, 50 mg.

GSK is also the sponsor of the nasal spray product BECONASE AQ® (beclomethasone dipropionate, monohydrate) Nasal Spray, 42 mcg. Like FLONASE, BECONASE is a metered-dose spray product that is formulated as a suspension of the active ingredient for topical administration to the nasal mucosa, and like FLONASE it is approved for use in the relief of the symptoms of seasonal or perennial allergic, and also nonallergic, rhinitis. *See* Tab 1, approved labeling. BECONASE is also approved for preventing the recurrence of nasal polyps following surgical removal. *Id.*

It has recently come to our attention that one or more ANDAs for generic copies of BECONASE are pending before the Agency. For all the reasons stated in the Petition, which apply equally to BECONASE, GSK hereby supplements the pending Petition to include as an additional "ACTION REQUESTED" that FDA refrain from approving any ANDAs for beclomethasone dipropionate nasal spray products until the guidance development process,

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including a sufficient opportunity for public review and comment, has been completed and a final guidance has issued.

Thank you for your consideration.

Respectfully submitted,

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Enclosure

cc: David M. Fox
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